

K960101

ISLAND BIOSURGICAL, INC.

DEC 16 1996

Feb 21, 1996

Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center (HFZ-401)  
9200 Corporate Blvd  
Rockville, MD 20850

Re: 510 (k) Summary of Safety and Effectiveness

Island Biosurgical Establishment  
Registration No.: 9009464  
K960101

Attention: Document Mail Clerk

The following is a summary of the information submitted in  
the complete 510(k) for the Island Biosurgical bolster.

Trade Name: Island Biosurgical Bolster  
Common Name: Surgical Bolster  
Classification Name: Mesh, Surgical, Polymeric

Substantial Equivalence: Marlex polypropylene mesh

Description: A preformed surgical mesh device with  
sutures woven along the edges.

Intended use: Supporting the endopelvic fascia in  
bladder neck surgery for stress incontinence.

Technological characteristics: No differences from the  
legally marketed  
polypropylene mesh.